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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,524	09/13/2006	Wolfgang H. Dillmann	UCSD1620-1	8043

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
11/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,524	DILLMANN ET AL.	
	Examiner	Art Unit	
	James (Doug) Schultz, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-9 and 11-29* is/are pending in the application.

4a) Of the above claim(s) *15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9,11-14 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/28/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed July 1, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 4, 2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The newly submitted application declaration of July 1, 2010 is accepted as being complete and proper.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 28, 2010 was filed before the mailing date of the instant action on the merits, and has met the requirements for consideration after mailing of a non-final rejection. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and a signed and initialed copy is enclosed herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11-14 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated against these claims for reasons of record set forth in the official action mailed March 4, 2010.

This rejection has been withdrawn against claims 1, 3, 5-8, and 27 in view of the evidence and statements of the declaration signed and submitted by Wolfgang Dillman on July 1, 2010. This rejection is maintained against claims 9, 11, and 28, insofar as these claims recite "preventing heart failure" comprising administering a sorcin encoding vector, and against claims 12-14 for reciting methods requiring the use of generic agents that modulate or upregulate sorcin expression. The Dillman declaration is not considered to provide evidence or reasoning commensurate in scope with the invention of the above claims.

While applicants have supplied evidence in the form of a declaration that is asserted to show that in vivo delivery of a sorcin encoding vector is indeed capable of increasing cardiac contractility, neither the declaration nor applicant's arguments address how the combination of the prior art and the data supplied in the specification and the declaration would enable one of ordinary skill to be able to prevent heart failure. It is maintained that one of skill would immediately understand that prevention of heart failure via gene therapy is a long-standing goal that has not been achieved to any meaningful degree in the art. It is also maintained that evidence in the instant specification and declaration showing that delivery of a sorcin encoding vector is

capable of increasing cardiac contractility is not sufficient evidence that prevention of heart failure via gene delivery has been or can be achieved with the present methods.

It does not appear that applicant's response addresses the issue of "preventing" as raised in the previous office action. However, it may reasonably be presumed that applicants might argue that the term "prevention" embraces a variety of meanings, including treatments that merely delay the onset of heart failure at one and of the prevention spectrum, to treatments that completely and totally eliminate the possibility of heart failure ever occurring at the opposite end of such a spectrum. Under such circumstances, and given the breadth of this term, it may be then be argued that the teaching of treatments which result in a reduction in heart failure would thus constitute species that fall within the genus of "preventing heart failure". Were this line of reasoning to be set forth, such arguments would not be convincing, since the teaching of treatments that might arguably fall within the scope of the term "prevention" as broadly stated above are not considered to be representative of the breadth of this term, which embraces full prevention as outlined above. It is set forth that the prior art and/or in the instant application are silent as to a teaching of full prevention, and that support for the full breadth of this term is thus lacking. Accordingly, this rejection is maintained against claims 9, 11, and 28 for this reason. Cancellation of the term "prevention" would obviate this aspect of the rejection.

Regarding claims 12-14 which are drawn to "agents" that may modulate or stimulate sorcin expression, it is noted that beyond the sorcin-expressing vectors, no evidence or reasoning has been presented either in the declaration or in the specification as filed that might demonstrate or suggest the enablement of the instantly claimed methods that rely upon the existence of agents beyond the disclosed vectors that have the claimed activity of modulating or upregulating sorcin.

The prior art also appears to be silent in regards to pharmaceutical agents that are capable of upregulating sorcin. While the specification teaches generic methods of screening for such sorcin modulators, the evidence in the Dillman declaration is silent regarding the existence of or use and enablement of such modulators. Accordingly, the declaration is not considered convincing since the evidence and reasoning therein is not commensurate in scope in regards to the use of pharmaceutical agents that upregulate sorcin beyond the sorcin-encoding gene carrying vectors disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 5, and 6, are rejected under 35 U.S.C. 102(a) as being anticipated by Suarez et al. ("Suarez"; applicant's IDS submitted September 28, 2010, "In vivo adenoviral transfer of sorcin reverses cardiac contractile abnormalities of diabetic cardiomyopathy", Am. J. Physiol. Heart Circ. Physiol., 2004 Jan; 286(1):H68-75, Epub. 2003 Sep 4.).

The claims of the instant invention are drawn to methods of increasing cardiac contractile function, comprising altering expression of sorcin in the subject's heart by administering a viral vector encoding sorcin to the subject. The claimed invention recites the use of viral vectors that are adeno- or adeno-associated in origin, or wherein the vector is administered directly into the heart, or wherein the heart is in a normal subject without heart disease.

Suarez et al. teach that adenoviral gene transfer of sorcin increases cardiac contractility in vivo. Suarez teaches delivery of their sorcin-encoding vector into the heart, and teaches that sorcin overexpression increases left ventricular pressure, max dP/dT, and min dP/dT compared to control.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-9, 11, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suarez et al. in view of Podsakoff et al. (U. S. Patent Number 6,335,011).

The invention is discussed above, further comprising wherein the heart has decreased contractile function prior to administration of the viral vector, or wherein the subject has diabetes mellitus. The instant invention further embraces methods of treating or preventing heart failure in a subject, wherein said administration may comprise administering a sorcin-expressing vector directly into the heart of the subject. The claimed invention also embraces methods of monitoring the therapeutic regimen for treatment comprising determining changes in sorcin expression during therapy, wherein said monitoring may be performed in conjunction with the methods of increasing contractility or methods of treating or preventing heart disease discussed above.

The teachings of Suarez have been discussed. Although Suarez does not actually teach treating heart disease in human subjects, or treating any subject that has decreased contractile function prior to such administration, or wherein said subject has diabetes, the teachings of Suarez would have been considered by one of ordinary skill in the art to directly lead to treatments of human-specific heart failure comprising delivery of sorcin expressing adeno- or adeno-associated vectors, since there is such a strong art recognized motivation to develop treatments for heart failure, and since the experiments of Suarez teach improving heart contractility using vectors to deliver sorcin to in vivo mouse models, which are considered in the art to be representative of human biology. It is prima facie obvious to extend such treatments to those that are experiencing decreased contractile function prior to treatment, or to those that have diabetes, particularly since the latter is a known and prevalent circulatory disease which often leads to heart failure. Since Suarez teaches that cardiac contractility may be regulated by sorcin, it also would have been considered obvious to monitor sorcin expression during therapy as a means for gauging the status of contractility in the heart during such therapy. Podsakoff is relied upon merely for a general teaching of gene therapy techniques that utilize adenovial vectors as such treatments might apply to muscle tissue. Accordingly, one of ordinary skill in the art would have considered the invention as a whole to have been prima facie obvious at the time the invention was made.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 28, 2010 prompted the new ground(s) of

rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James (Doug) Schultz, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz, PhD/
Primary Examiner, Art Unit 1633